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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/899,432 | 07/06/2001 | Robert Kleiman | 511-051 | 3374 |

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| EXAMINER | |
|---|---|
| JIANG, SHAOJIA A | |
| ART UNIT | PAPER NUMBER |
| 1617 | 11 |

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/899,432 | KLEIMAN ET AL. | |
| | Examiner | Art Unit | |
| | Shaojia A. Jiang | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *38-39, 41-42, 44-45, 47-48, 50-51, 53-54, 56-57, 59-60, 62-63, 65-66, 68-69, 71-72, 74-75, 77-78, 80-81, and 83-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .



Continuation of Disposition of Claims: Claims pending in the application are
2,3,5,6,8,9,11,12,14,15,17,18,20,21,23,24,26,27,29,30,32-33,
35,36,38,39,41,42,44,45,47,48,50,51,53,54,56,57,59,60,62,63,65,66,68,69,71,72,74,75,77,78,80,81,83,84,86,87,89 and 90.

Continuation of Disposition of Claims: Claims rejected are
2,3,5,6,8,9,11,12,14,15,17,18,20,21,23,24,26,27,29,30,32,33,35,36,86,87,89 and 90.

## DETAILED ACTION

Applicant's preliminary amendment in response to the Restriction Requirement in Paper No. 9, submitted January 23, 2003 is acknowledged, wherein claims 1, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31, 34, 37, 40, 43, 46, 49, 52, 55, 58, 61, 64, 67, 70, 73, 76, 79, 82, 85, and 88 are cancelled and all rest claims are amended. Currently, claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 38-39, 41-42, 44-45, 47-48, 50-51, 53-54, 56-57, 59-60, 62-63, 65-66, 68-69, 71-72, 74-75, 77-78, 80-81, 83-84, 86-87, and 89-90 are pending in this application.

Applicant's preliminary amendment in Paper No. 10, submitted March 3, 2003 is acknowledged, wherein the instant specification has been amended as to page 2, the first paragraph.

### *Election/Restrictions*

Applicant's election in response to the Restriction Requirement with traverse of the invention of Group I, claims 1-36 and 85-90, in Paper No. 8 submitted January 23, 2003 is acknowledged.

The traversal is on the ground(s) that all these inventions have the effect of antiviral activity, both preventive and treatment, employing the same composition. This is not found persuasive. As discussed in the Requirement for Restriction mailed October 1, 2002, the inventions of Group I, II, and IV have different functions. Thus, these inventions are seen to be separate and distinct inventions properly restricted from each other. Therefore, the search for all inventions would place an undue burden on the

Office. Note regarding the classification of the inventions herein that the search is not limited to the patent files.

Moreover, the search field for a composition is non-coextensive with the search field for a method of treating of preventing herein employing the same composition. A reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103. The composition and method herein have separate consideration as to patentability.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90 will be examined on the merits herein. The requirement is still deemed proper and is therefore made FINAL.

Claims 38-39, 41-42, 44-45, 47-48, 50-51, 53-54, 56-57, 59-60, 62-63, 65-66, 68-69, 71-72, 74-75, 77-78, 80-81, and 83-84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

***Claim Objection***

Claims 14-15, 17-18 and 20-21, 23-24 are objected to under 37 CFR 1.75(c), as being duplicated of one another. Appropriate correction is required.

Claims 2-3, 5-6, 8-9, 11-12 are objected to for minor informalities. A word, i.e., "of", is missing in the phrase between "A method" and "treating". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "relative" in claims 5-6, 11-12, 17-18, 23-24, 29-30, 35-36 and 89-90 is a relative term which renders these claims indefinite. The term "relative" is not defined in the specification.

The phrase "from 0.1 to 25 percent by weight" is recited twice (repeated one after another) in claim 8. Thus, the claim is unclear as to why this phrase is repeated for defining the concentration of the instant alcohols.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the

claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, all claims herein recite the broad recitation "monounsaturated alcohols" and the claim also recites particular alcohols "octadecenol, ...."; claims 3, 9, 15, 21, 27, 29-30, 35-36, 86-87, and 89-90 recite the broad recitation "alky group or other aliphatic group" and the claim also recites "preferably.." which is the narrower statement of the range/limitation.

The phrase "mammal suspected..." in claims 14, 20, 26, 32, and 86 renders claims 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 35-36, 86-87, and 89-90 indefinite. The phrase "mammal suspected..." is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392, PTO-1449 submitted July 6, 2001) in view of ARQUETTE et al.

(WO 9920224, PTO-892) and Katz (4,874,794, PTO-1449 submitted July 6, 2001) and Katz (5,070,107, PTO-1449 submitted July 6, 2001)

Katz et al. (5,952,392) discloses that long chain fatty acids broadly including oleic acid (C18, one double bond) or monounsaturated long chain alcohols broadly (e.g., C18-C28) in their effective amounts with a physiologically compatible carrier are useful in a pharmaceutical composition for topical application and intramuscular and intravenous injections, and methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity. See abstract, col.1 lines 10-15 and 20-47; col.2 lines 12-15; col.3 lines 18-21; Examples 14-15 at col.22-23.

The prior art does not expressly disclose the employment of monounsaturated long chain alcohols in combination with long chain fatty acids salts herein in a pharmaceutical composition, which may further comprising the fatty acid esters herein, in a method for treating virus-induced and inflammatory disease of skin and membranes. The prior art does also not expressly disclose the effective amounts of active agents in the composition herein to be administered.

Arquette et al. (WO 9920224) discloses a pharmaceutical composition comprising the instant fatty alcohols at least 10% by weight (see particularly abstract and page 3 lines 15-22), jojoba oil (known to contain the instant fatty acids, see page 4 entirely), and the instant fatty acid esters in their various percentages (see page 4-8) with a physiologically compatible carrier for topical applications (see abstract and claims 1-12

Katz et al. (4,874,794) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C20-C26) with a physiologically compatible carrier in a pharmaceutical composition for topical application for methods of treating viral infections and skin inflammations are 0.1 to 25 percent by weight. See abstract, col.3 lines 63-68, claims 1-2.

Katz et al. (5,070,107) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C27-C32) with a physiologically compatible carrier in a pharmaceutical composition for topical application and intramuscular and intravenous injections for methods of treating viral infections and skin inflammations are 0.1 mg to 2 g/per 50kg of body weight. See abstract, col.3 lines 63-68, claims 1-2.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant monounsaturated long chain alcohols in combination with the instant fatty acids salts herein in a pharmaceutical composition, which may further comprising the instant fatty acid esters herein, in methods for treating virus-induced and inflammatory disease of skin and membranes, and to optimize the effective amounts of active agents in the composition herein to be administered.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant monounsaturated long chain alcohols in combination with the instant fatty acids salts herein in a pharmaceutical composition, which may further comprising the instant fatty acid esters herein, in methods for treating virus-induced and inflammatory disease of skin and membranes since long chain fatty acids broadly or monounsaturated long chain alcohols broadly in their effective amounts

with a physiologically compatible carrier are known to be useful in pharmaceutical compositions for topical application and intramuscular and intravenous injections, for methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity based on Katz et al. Moreover, the instant fatty alcohols at least 10% by weight, the instant fatty acids, and the instant fatty acid esters in their various percentages with a physiologically compatible carrier are known to be useful in a pharmaceutical composition for topical applications according to Arquette et al. Therefore, one of ordinary skill in the art would have reasonably expected that combining the instant fatty alcohols, the instant fatty acids, and the instant fatty acid esters taught in Arquette et al. in a pharmaceutical composition to would improve the therapeutic effect for treating virus-induced and inflammatory disease of skin and membranes since these components are known to be useful in treating virus-induced and inflammatory disease of skin and membranes.

Since all active composition components herein are known to useful to treat virus-induced and inflammatory disease of skin and membranes, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of known effective amounts of known active agents to be administered according the disclosures of Katz et al. and Arquette et al., is considered well within the

skill of artisan. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

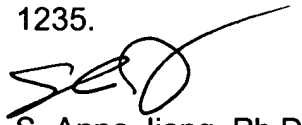
Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
May 14, 2003